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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,773	03/30/2001	Robert F. Hofmann	TORQ-0002 (103336.00004)	6970

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EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/822,773

Applicant(s)

Hofmann et al.

Examiner

John Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 18, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 7
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 1-55 are pending in this application.

Applicant's election without traverse of (i) geranylgeraniol, (ii) DMSO, (iii) porphyrin, and (iv) benzoquinone in Paper No. 8 (11/18/02) is acknowledged.

In claim 1, line 5, "a alkene" should be changed to --- an alkene --- .

Claims 32-52 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Method claims 32-52 depend on claim 30 or depend on claims that depend on claim 30. However, claim 30 is directed to an article of manufacture, not a method for treating a patient.

Claims 1-23, 25-28, 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) Claims 1-23 and 25-28 are readable on "an aromatic redox compound" with no further clarification. The Examiner requests further clarification as to what constitutes an aromatic redox compound that falls within the scope of the invention. The term "redox" refers to a reaction that involves the transfer of electron between two chemicals. Hence, a compound can be an electron donating or accepting substance. Therefore, it is not understood what is meant by "an aromatic redox compound" in the present context, i.e. as a component of a system that contains peroxidic species or oxidized alkenes, solvent, dye, and electron donors for treating

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coronary arteriosclerosis. Besides the quinones that are disclosed in the specification and other claims, what else is covered by this term?

(2) In claims 8-9, "the isoprenoid" lacks antecedent basis. Same problem in claims 37-38.

(3) In claims 10 and 39, it is not clear what is meant by "fixed oil-, ester, fatty acid-, or ether-containing olefin."

(4) In claim 11, "the oxygen-containing oxidizing agent" lacks antecedent basis. Claim 11 depends on claim 1. While a mixture of ozone and oxygen is recited in the independent claim 1, an oxygen-containing oxidizing agent is not recited in said independent claim. Same problem in claims 12, 40-41.

(5) In claims 20-21, the terms "electroportation pulse," "phonon," "plasma pulse," "gravitational pulse," and "continuous flow excitation" are unclear with respect to activating a dye such as porphyrin or rose bengal. What exactly are such energy sources, how are they utilized/harnessed and how do they, in practical terms, achieve activation of dyes?

(6) What is the nature and makeup of "plasma" in claims 27 and 42? In claim 27, it is an electron donor, in claim 42 it is a solvent. What exactly is "plasma" according to applicant?

Claims 1-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific compositional ingredients and percentages shown on specification pages 15 and 16 (Examples 3A and 3B), does not reasonably provide enablement

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for the more broadly claimed subject matter, including those without specific percentages for components. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The nature of the invention is in the treatment of patients with coronary diseases. The state of the prior art is full of conflicting evidence with respect to peroxides or oxidative products. Peroxides and certain “dyes” such as hemin are known to contribute to the peroxidation of lipoproteins, which plays an important role in atherogenesis (Chemical Abstracts 125:9418). On the other hand, peroxides have been reported (Chemical Abstracts 105:223647) to relax rat aortic rings contracted with another agent – the relaxation is however blocked by methylene blue, one of the dyes recited by applicant in instant claim 19.

The relative skill of those in this art is quite high. After all, they are involved in providing treatments to patients suffering from coronary diseases. The unpredictability of the art in providing treatments for coronary diseases with peroxides or oxidative products of alkenes is very high. The two Chemical Abstracts, *supra*, show unpredictable functions and interactions when peroxides and/or dyes are administered.

The breadth of the claims has already been discussed. It is very broad. There is no percentage limitation for any of the components, even though the specification only tested a composition or article that contains 0.54 wt% oxidative product, 98 wt% solvent (DMSO), 0.83 wt% porphyrin dye, 0.39 wt% another dye, and 0.24 wt% “aromatic redox compound” (quinone).

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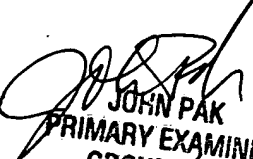
Clearly, such specification examples do not provide guidance to use far broader range of percentages and other types of compounds for each component. Given the different ways peroxides and other oxidative species are known or expected to behave and interact with dyes in patients suffering from coronary diseases, taken with the difficulty and high risks involved in treating coronary diseases and events, the limited examples and guidance provided by the specification are not sufficient to enable the skilled artisan to utilize broader percentages, proportions and divergent components without undue experimentation.

Facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 7:30 AM to 4 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


JOHN PAK
PRIMARY EXAMINER
GROUP 1600